

## REMARKS

The Office Action of July 25, 2008, has been received and reviewed. Applicants note that a Notice of Appeal was filed in the present application on January 8, 2009. The Request for Continued Examination filed herewith has the effect of withdrawing the application from appeal and reopening prosecution (M.P.E.P. § 1215.01). The claims are to be amended as previously set forth. New claims 22-25 are presented herein. Basis for new claims 22-26 can be found throughout the Specification and more specifically at ¶¶ 9, 10, 21, 54-60, 67, 76, and 80 of the Specification as published, in FIGs. 1-3, and in original claims 1, 13, 19, and 20. All amendments are made without prejudice or disclaimer. No new matter has been presented. Reconsideration is respectfully requested.

Claims 1-19 and 21 stand rejected under 35 U.S.C. § 103(a) as assertedly rendered obvious by Krone *et al.* (U.S. Pat. 5,391,696) (hereinafter “Krone”) in view of Suzuki *et al.* (U.S. Pat. 6,015,789) (hereinafter “Suzuki”) and in further view of Ishino *et al.* (Chem. Pharm. Bull. 1992, 40, 3036-3041) (hereinafter “Ishino”) and Maggi *et al.* (Biomaterials 2002, 23, 1113-1119) (hereinafter “Maggi”) (collectively hereinafter “the references”). Applicants respectfully traverse the rejections as hereinafter set forth.

To establish a *prima facie* case of obviousness, the prior art itself or “the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]” at the time of the invention are to have taught or suggested the claim elements. Additionally, the Examiner must determine whether there is “an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741, 167 L.Ed.2d 705, 75 USLW 4289, 82 U.S.P.Q.2d 1385 (2007). Further, rejections on obviousness grounds “cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* at 1741, quoting *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006). “Often, it will be necessary for a [fact finder] to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion

claimed . . . . To facilitate review, this analysis should be made explicit.” *Id.* Furthermore, to establish a *prima facie* case of obviousness there must have been a reasonable expectation of success. M.P.E.P. § 2143.02. Underlying the obvious determination is the fact that statutorily prohibited hindsight cannot be used. *KSR*, 127 S.Ct. at 1742.

Applicants submit that the combination of the references cannot render obvious the claims as the references and/or the inferences and creative steps that a person of ordinary skill in the art would have employed at the time of the invention do not teach or suggest all the claim elements. Specifically, the references fail to teach or suggest that the pharmaceutical composition “does not comprise a barrier structure” as recited by amended claim 1 or “wherein the compressed tablet does not comprise a barrier structure” as recited by amended claim 14. Basis for the amendments to claims 1 and 14 can be found throughout the Specification and at least in ¶¶ 9 and 10 of the Specification as published and in original claim 1.

According to the summary of the references provided at pages 2 and 3 of the Office Action, Ishino is the only reference that teaches pulsatile release of a pharmaceutically active material. However, Ishino accomplishes that that pulsatile release through the use of a PEG barrier structure (Ishino at FIG. 1; pg. 3036, col. 2; pg. 3037, col. 2; and pg. 3039, col. 2 through 3040, col. 2). The remainder of the references being unrelated to pulsatile release, do not contradict Ishino regarding the use of barrier structures to achieve pulsatile release. Consequently, the references cannot render obvious claims 1 and 14 as the references and/or the inferences and creative steps that a person of ordinary skill in the art would have employed at the time of the invention do not teach or suggest all the claim elements of claims 1 and 14.

In addition, the references cannot render obvious claim 19, as references and/or the inferences and creative steps that a person of ordinary skill in the art would have employed at the time of the invention do not teach or suggest all the claim elements of claim 19. Specifically, claim 19 recites “a majority of the pharmaceutically active material is released in an initial burst and a second burst.” As is apparent in FIGs. 10 and 12 of Ishino, the tablet dissolves in a single burst and not in an initial and second burst as recited by claim 19. The remainder of the references also does not teach initial and second burst pulsatile release and thus fail to remedy the lack of teaching identified in Ishino. Consequently, the references cannot render obvious claim 19 as the references and/or the inferences and creative steps that a person of ordinary skill in the

art would have employed at the time of the invention do not teach or suggest all the claim elements of claims 19.

For at least the foregoing reasons, applicants respectfully request the withdrawal of the rejections of claims 1, 14, and 19 and allowance of same.

In addition, the nonobviousness of independent claims 1 and 14 preclude a rejection of claims 2-13, 15-18, and 20, which depend from one of claims 1 and 14 or otherwise incorporate all the elements of claim 1, because a dependent claim is obvious only if the independent claim from which it depends is obvious. *See* MPEP § 2143.03. Therefore, the applicants request that the Examiner withdraw the 35 U.S.C. § 103(a) obviousness rejections of claims 2-13, 15-18, and 20 and notify applicants of the allowance of same.

#### CONCLUSION

In light of the above amendments and remarks, applicants respectfully request reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.



Respectfully submitted,

Daniel J. Morath, Ph.D.  
Registration No. 55,896  
Attorney for Applicants  
TRASKBRITT, P.C.  
P.O. Box 2550  
Salt Lake City, Utah 84110-2550  
Telephone: 801-532-1922

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